

### **Remarks/Arguments**

Applicants have received and carefully reviewed the Office Action of the Examiner mailed October 6, 2008. Currently, claims 11-20 remain pending. Claims 11-20 have been rejected. Favorable consideration of the following remarks is respectfully requested.

### **Claim Rejections – 35 USC § 103**

Claims 11-17, 19, and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Frid et al. (U.S. Patent No. 6,159,228), hereinafter Frid, in view of Roberts et al. (U.S. Patent No. 5,984,964), hereinafter Roberts. After careful review, Applicant must respectfully traverse this rejection.

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03). As will be seen in Fig. 2-6 of Frid, the device described by Frid appears to require the presence of a flexible pusher (10) interposed between catheter (9) and sheath (2) in order to maintain endoprosthesis (1) in position with respect to catheter (9) and radio-detectable zones (12,13) as sheath (2) is withdrawn allowing endoprosthesis (1) to further expand away from catheter (9). It would appear that endoprosthesis (1), said to be inserted in its radially contracted shape into a sheath (2), is constrained by sheath (2) which employs a reinforced framework (3) to contain the sheath and resist its outward expansion. The presence of this additional concentric element appears to undesirably require a larger sheath (2) than would be required by the construction of the present invention and the additional layer would be expected to contribute undesirable stiffness to the device which must be maneuvered to the deployment site. Omission of this interposed flexible pusher element while retaining the function is an indicia of unobviousness. (MPEP 2144.03, II., B.)

The Examiner has acknowledged that Frid does not disclose inner and outer shaft portions having a second position wherein the inner shaft engages the distal end of the

outer shaft and turns to Roberts to provide that claim element, citing Fig. 1A, reproduced in part below.

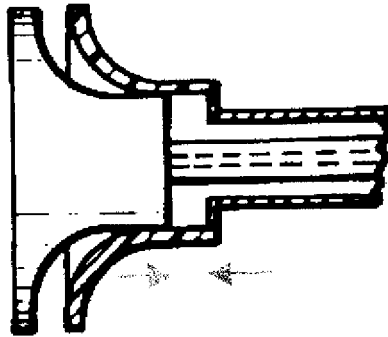


Fig. 1A of Roberts is characterized as showing the sheath as retracted to expose the stent. As indicated by the opposed arrows above, the distal end of handle (12) is displaced well proximal of the distal end of handle (25) [unidentified in the figures, but said to be attached to sheath (20)]. The Examiner may be tempted to suggest that handle (12) could be further urged distally into handle (25), however closer examination will show that the proximal handle flanges are separated by a smaller gap than the gap between the possible contact surfaces in question and approximately 37% of the indicated gap would remain even if the proximal flanges were in contact. Further, as depicted in the cited Fig. 1A, the stent would have been fully released when handle (12) first contacted the proximal bore of handle (25). Even if the handles of Roberts could be positioned so that the distal end of handle (12) is in contact with the distal end of handle (25), the gap between the distal end of the sheath and the proximal end of the stent would appear to be more than 20% of the length of the stent. The device of Roberts appears to be incapable of contributing to the deployment accuracy of Frid, contrary to the Examiner's suggestion that the combination would allow the operator to know when the stent had been released and one of ordinary skill in the art would not have been motivated to turn Roberts in an attempt to improve the device of Frid.

The Examiner has further acknowledged that the claimed invention differs from Frid in calling for the exterior tube to be stepped and has suggested that this is an obvious matter of design choice of an alternate means to join the exterior tube to the hub. Frid

teaches over-moulding of Luer 7 (col. 6, lines 15-17) to determine the position of the end of the sheath relative to the radio-detectable zones. The structure of the pending claim allows the surgeon to select components such as flush valve (88) and seal (90) and to assemble them as desired while the stepped tube allows the user to secure the relatively small sheath (96) directly to the large easy-to-handle outer shaft. (Paragraph [0037].) Contrary to the Examiner's proposed motivation of "maintaining the necessary small diameter at the distal end of the tube", the use of a wide proximal end of the stepped tube allows the connection to be made easily while maintaining a smaller diameter in that portion of the tube which enters the vessel. Accordingly, one of ordinary skill in the art would prefer to retain the component choices and ease of assembly allowed by the pending structures and would not turn to the assembly method of Frid which does not appear to support those choices.

Turning next to the rejection of claims 10 and 18, Applicant respectfully notes that claim 10 has been canceled and claim 18 is dependent from claim 11. As discussed above, claims 11, 19, and 20 were acknowledged to be nonobvious over Frid on several grounds and it has been shown that the deficiencies of the Frid reference are not overcome by Roberts, both for the reason that Roberts fails to provide elements missing from Frid and because one of ordinary skill in the art would not be motivated to make the proposed modifications. Therefore, Frid in view of Roberts does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness and the combination appears to fail the *Graham* inquiry.

"the *Graham* factors, including secondary considerations when present, are the controlling inquiries in any obviousness analysis. The *Graham* factors were reaffirmed and relied upon by the Supreme Court in its consideration and determination of obviousness in the fact situation presented in *KSR*, 550 U.S. at \_\_\_, 82 USPQ2d at 1391 (2007)." (MPEP 2141, II.)

Applicant respectfully requests that the rejections of independent claims 11, 19, and 20 be withdrawn.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

Additionally, for similar reasons, as well as others, claims 12-18, which depend from claim 11 and include significant additional limitations, are believed to be patentable over Frid in view of Roberts and Applicant respectfully requests withdrawal of the rejections.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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